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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,144	01/15/2004	David Y. Kim	ILL01-010-US	7197

43320 7590 07/14/2006

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EXAMINER	
SONG, MATTHEW J	

ART UNIT	PAPER NUMBER
1722	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,144	KIM ET AL.	
	Examiner	Art Unit	
	Matthew J. Song	1722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 32-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-17 and 32-45 in the reply filed on 4/27/2006 is acknowledged.

2. Claims 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-17 and 32-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bray et al (US 6,406,903 from IDS 12/14/04) in view of Shu et al ("In situ measurement and dynamic control of the evaporation rate in vapor diffusion crystallization of proteins" from IDS 12/14/04).

In a method of controlling crystal growth, note entire reference, Bray et al teaches a system which screens up to 40 different evaporation profiles simultaneously using growth chambers in which the growth solution is deployed as a hanging drop (col 6, ln 30-67 and Fig 4). Bray et al also linear evaporation profiles were performed to determine the effect of evaporation rate on crystal growth from solutions of protein and crystallizing agent solutions (col 8, ln 5-67), this clearly suggests applicant's removing solvent from a plurality of solutions containing substantially the same concentration of a compound simultaneously and at different rates to form a solid. Bray et al specifically teaches rates of 0.041, 0.083, 0.2, 0.34, 0.45 and 1.25 microliters/hr (col 8, ln 30-40). Bray et al also teaches the approach to finding suitable conditions that yield high quality protein crystals predominately has been a trial and error process, where more than one thousand crystallization conditions are typically screened (col 2, ln 40-65).

Bray et al does not teaches removing solvent from a plurality of solutions containing different concentration of a compound simultaneously at substantially the same rate.

In a method of dynamic control of protein crystallization, note entire reference, Shu et al teaches automatically obtaining equilibration curves under different crystallization conditions (Abstract). Shu et al also teaches equilibration curves are obviously different for different concentrations, while the other conditions are kept identical (pg 284), this clearly suggests applicant's removing solvent from a plurality of solutions containing different concentration of a

compound simultaneously at substantially the same rate because the other conditions are kept identical. Shu et al specifically teaches concentrations of 6, 9, 15 and 21% (pg 284).

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bray et al by determining the equilibration curves for different concentration while the other conditions are kept identical, as taught by Shu et al to optimize the process of protein crystallization (Abstract).

Referring to claims 2-3 and 33-34, the combination of Bray et al and Shu et al is silent to the order of removing solvent from the first and second solutions. The selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (MPEP 2144.03).

Referring to claims 4-6 and 35-37, the combination of Bray et al and Shu et al is silent to the claimed variation of concentration and the claimed the variation in the rate of removing solvent. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray et al and Shu et al by using the claimed variations to obtain more experimental data to minimize the need for extrapolation for improved accuracy in the results.

Referring to claims 7-8 and 38-39, the combination of Bray et al and Shu et al teaches a hanging drop crystallization process. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray et al and Shu et al to complete the process by removing all of the solution until only the crystal remains.

Referring to claims 9 and 40, the combination of Bray et al and Shu et al is silent to the concentration of the second plurality of solutions is substantially the same as the concentration of

one of the solutions of the first plurality of solutions. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray et al and Shu et al by using the optimal concentration obtained from the first plurality of solution.

Referring to claim 10, the combination of Bray et al and Shu et al is silent to the rate of removing solvent from the first plurality of solutions is substantially the same as the rate of removing solvent from one solutions of the second plurality of solutions. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Bray et al and Shu et al by using the optimal rate of removing solvent obtained from the second plurality of solution.

Referring to claims 11-15 and 41-44, the combination of Bray et al and Shu et al teaches protein crystallization comprising a precipitate and water ('903 col 1, ln 25-45 and col 5, ln 10-20).

Referring to claims 16-17 and 45, the combination of Bray et al and Shu et al teaches a system screens up to 40 profiles simultaneously, this clearly suggests at least six.

Referring to claim 32, the combination of Bray et al and Shu et al teaches removing a solvent at substantially the same rate from plurality of solutions containing different concentration (Shu et al pg 284), this clearly suggests applicant's third plurality of solutions. The combination of Bray et al and Shu et al also teaches removing solvent at different rates from a plurality of solutions at the same concentration ('903 col 8, ln 1-67).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Grabitech ("Design of Experiments Optimization Strategies") teaches one variable at a time approach for experimental optimization, sequential design of experiments, simultaneous design of experiments, and a combination of sequential and simultaneous design of experiments (pg 1-2).

Forsythe et al ("Vapor diffusion, nucleation rates, and the reservoir to crystallization volume ratio" from IDS 12/14/04) teaches vapor diffusion rates is dependant on concentration of solutes present and these factors can be experimentally optimized (pg 1601). Also performing same concentration experiments at different rates (pg 1603).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Song whose telephone number is 571-272-1468. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew J Song
Examiner
Art Unit 1722

MJS
July 10, 2006

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